

REMARKS

In light of the following remarks, reconsideration of the present application is respectfully requested. Claims 1-3, 6, 8-15, 17-18 and 21-23 are pending.

Rejections under 35 U.S.C. § 103

1. Claims 15, 22, 1-3, 9-10, 14, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer et al. (US 6,556,695), hereinafter "Packer," in view of Leiper (US 6,128,002) hereinafter "Leiper," and further in view of Rose (US 2002/0176608), hereinafter "Rose," and Hemler et al. (A System for Multimodality Image Fusion), hereinafter "Hemler." Applicants traverse this rejection for the following reasons.

A. Packer, Leiper, Rose and Hemler fail to disclose or suggest an interface for "electroanatomical 3D mapping data and 3D image data," as recited in claim 15.

FIG. 1 of Packer illustrates a MRI apparatus. Col. 3, lines 51-67 of Packer relate to imaging modality for producing a high resolution model (CT, MRI, ultrasound). Col. 2, lines 14-60 of Packer disclose acquiring image data of the subject anatomy and reconstructing an image which is a high resolution model of the subject anatomy; performing a medical procedure in which the subject anatomy is imaged in real-time by acquiring low resolution images at a high frame rate; registering the high resolution model of the subject anatomy with each acquired low resolution image; and displaying images of the registered high resolution model of the anatomy.

The Examiner relies on the above-cited portions of Packer to teach the "interface" of claim 15. In addition, the Examiner provides a generic statement, on page 3 of the Office Action, that "Packer discloses a system that perform an imaging method therefore the system must have at least one input interface for

electroanatomical 3D mapping data and 3D image data." However, as demonstrated above, Packer acquires low resolution images, not 3D images.

Moreover, the Examiner provides that Packer "must" have an interface for 3D mapping and image data. However, in establishing that an element is inherent in a reference, the missing element must be necessarily present in the apparatus described in the reference(s) such that the presence of these elements would be recognizable by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Examiner has not established that an interface for 3D mapping and image data is inherent to the disclosure of Packer because another interface can be used. For example, Packer even goes as far to disclose an interface for low resolution images, but does not disclose an interface for 3D mapping data and 3D image data.

Leiper, Rose and Hemler fail to cure the deficiencies of Packer described above.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest an interface for "electroanatomical 3D mapping data and 3D image data," as recited in claim 15.

B. Packer, Leiper, Rose and Hemler fail to disclose or suggest "a registration module ... for automatic correlation of the electroanatomical 3D mapping data and the selected 3D image data," as recited in claim 15.

FIG. 8 of Packer illustrates a flowchart for producing a high resolution, large field of view images in real-time on the display, "overlaying devices on image (242)" and an arrow from block 242 to the beginning. Col. 9, line 21 – col. 10, line 36, describes the flowchart (FIG. 8), without referring to any electrophysiological data. The cited text passages or figures do not describe how electrophysiological data are merged with the anatomic model.

The Examiner relies on Packer to teach the "registration module" of claim 15. However, Packer fails to disclose or suggest "a registration module ... for automatic correlation of the electroanatomical 3D mapping data and the selected 3D image data." In other words, Packer discloses a registration module designed for correlation of high resolution 2D, 3D or 4D model data with acquired low resolution ultrasonic image data. The low resolution image data are not electroanatomical 3D mapping data.

Leiper, Rose and Hemler fail to cure the deficiencies of Packer described above.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest "a registration module ... for automatic correlation of the electroanatomical 3D mapping data and the selected 3D image data," as recited in claim 15.

C. Packer, Leiper, Rose and Hemler fail to disclose or suggest "automatic correlation," as recited in claim 15.

Packer in col. 12, line 35 – col. 13, line 15 discloses that the location of the electrodes is registered manually with the high resolution image. "This is done by aiming the ultrasonic transducer 30 at each electrode 268, placing a cursor on an electrode pictured in the image, and typing in the electrode number."¹

Without this manual registration, it would not be possible to assign the measured activation in form of a color modulation of the appropriate pixel. Further, sensing electrical signals in Packer is not "3D mapping" as claimed, since the electrical signals produced by the electrodes of Packer (268, FIGS. 9-10) indicate the relative timing of the signals during cardiac cycle. As such, they cannot be regarded as electroanatomical 3D mapping data, but only as voltage over time signals.

¹ Col. 12, lines 52-61 of Packer.

Additionally, the arrow from block 242 to the beginning (FIG. 8) does not mean that the high resolution model with the overlaid electrophysiological data is input to the registration procedure with the real-time image.

The arrow means that the displayed image is continuously updated, i.e. a new real-time image is registered with a newly selected high resolution image (according to the ECG phase) and this image is overlaid again with the electrophysiological data by modulating the pixel color. Therefore, Packer does not disclose an “automatic registration” of the 3D image data and electroanatomical 3D mapping data.

Leiper, Rose and Hemler fail to cure the deficiencies of Packer described above.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest “automatic correlation,” as recited in claim 15.

D. Packer, Leiper, Rose and Hemler fail to disclose or suggest “surface matching the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data,” as recited in claim 15.

As admitted by the Examiner on page 3 of the Office Action dated April 13, 2010, Packer fails to disclose any “surface matching.” However, the Examiner relies on Rose and Hemler to teach this feature of claim 15.

Rose fails to teach or fairly suggest any “surface profiling” that is concerned with anatomy of living organisms. Rose is directed to surface-profiling of road surfaces.

There is no disclosure or suggestion in Packer and/or Rose to combine them. A statement that modifications of the prior art to meet the claimed invention would have been within the skill of a person of ordinary skill in the art at the time of the invention is not sufficient to establish *prima facie* obviousness without some objective to do so (MPEP § 2143.01). In the present case, the Examiner is using

impermissible hindsight to reconstruct the elements of the claims. There is no objective reason one of ordinary skill in the art at the time of the invention would seek to modify the elements of the reference and to do so would require such innovation as to be inventive.

Further, the teaching or suggestion to modify the reference and the reasonable expectation of success must both be found in the prior art, and not based on Applicants disclosure (MPEP § 2143). In making an assessment of the differences between the prior art and the claimed subject matter, 35 U.S.C. § 103 specifically requires consideration of the claimed invention “as a whole.” The “as a whole” instruction in 35 U.S.C. § 103 prevents evaluation of the invention on a part-by-part basis. Without this important requirement, an obviousness assessment might break an invention into its component parts, then find a prior art reference corresponding to each component. This line of reasoning improperly imports hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components (*Ruiz v. A.B. Chance Co.*, 357, F.3d 1270, 1275, (Fed. Cir. 2004)).

“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Hemler fails to cure the deficiencies of Packer, Leiper and Rose. More specifically, Hemler discloses a 3-D surface matching technique. However, a combination of Packer and Hemler (assuming they could be properly combined, which Applicants do not admit) would not result in “surface matching a 3D surface profile from 3D image data with a 3D surface profile from 3D mapping data.”

As stated above, Packer matches low resolution ultrasonic image data. Consequently, a combination of Packer and Hemler may result in using the 3D surface matching as disclosed in Hemler with low resolution image data as

disclosed in Packer because Packer only discloses and/or suggests matching low resolution image data.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest "surface matching the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data," as recited in claim 15.

Claim 1 is a separate independent claim from claim 15, wherein claim 1 contains its own individual limitations. Each independent claim should be interpreted solely based upon limitations set forth therein. However, claim 1 is patentable for at least reasons somewhat similar to those set forth above regarding claim 15. Claims 2-3, 9-10 and 14 are patentable based at least on their dependency on claim 1. Claims 18 and 22 are patentable at least by virtue of its dependency on claim 15.

Therefore, Applicants respectfully request that the rejections of claims 15, 22, 1-3, 9-10, 14 and 18 under 35 U.S.C. § 103 be withdrawn.

2. Claims 17, 21, and 6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler, and Williams et al. (DE 19953308-A1), hereinafter "Williams".

The Examiner correctly acknowledges that the features of claims 17, 21, and 6 are absent from Packer, Leiper, Rose and Hemler, but alleges that these features are taught by Williams, thereby rendering claims 17, 21, and 6 obvious to one of ordinary skill at the time of the invention. Even assuming *arguendo* that the features of claims 17, 21, and 6 are taught by Williams (which Applicants do not admit) and that Williams could be properly combined with Packer, Leiper, Rose and Hemler (which Applicants do not admit), Packer, Leiper, Rose, Hemler and Williams are still deficient with respect to the above-described features of claims 15 and 1.

Thus, even in combination, Packer, Leiper, Rose, Hemler and Williams fail to render claims 17, 21, and 6 obvious.

3. Claims 23 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler and Hughes et al. (US 7,233,340), hereinafter "Hughes."

The Examiner correctly acknowledges that the features of claims 23 and 13 are absent from Packer, Leiper, Rose and Hemler, but alleges that these features are taught by Hughes, thereby rendering claims 23 and 13 obvious to one of ordinary skill at the time of the invention. Even assuming *arguendo* that the features of claims 23 and 13 are taught by Hughes (which Applicants do not admit) and that Hughes could be properly combined with Packer, Leiper, Rose and Hemler (which Applicants do not admit), Packer, Leiper, Rose, Hemler and Hughes are still deficient with respect to the above-described features of claims 15 and 1. Thus, even in combination, Packer, Leiper, Rose, Hemler and Hughes fail to render claims 23 and 13 obvious.

Therefore, Applicants respectfully request that the rejections of claims 23 and 13 under 35 U.S.C. § 103 be withdrawn.

4. Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler, and Schweikard et al. (US 6,144,875), hereinafter "Schweikard."

The Examiner correctly acknowledges that the features of claim 8 are absent from Packer, Leiper, Rose and Hemler, but alleges that these features are taught by Schweikard, thereby rendering claim 8 obvious to one of ordinary skill at the time of the invention. Even assuming *arguendo* that the features of claim 8 are taught by Schweikard (which Applicants do not admit) and that Schweikard could be

properly combined with Packer, Leiper, Rose and Hemler (which Applicants do not admit), Packer, Leiper, Rose, Hemler and Schweikard are still deficient with respect to the above-described features of claim 1. Thus, even in combination Packer, Leiper, Rose, Hemler and Schweikard fail to render claim 8 obvious.

Therefore, Applicants respectfully request that the rejection of claim 8 under 35 U.S.C. § 103 be withdrawn.

5. Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler, and Krishnan (US 6,771,262), hereinafter "Krishnan".

The Examiner correctly acknowledges that the features of claim 11 are absent from Packer, Leiper, Rose and Hemler, but alleges that these features are taught by Krishnan, thereby rendering claim 11 obvious to one of ordinary skill at the time of the invention. Even assuming *arguendo* that the features of claim 11 are taught by Krishnan (which Applicants do not admit) and that Krishnan could be properly combined with Packer, Leiper, Rose and Hemler (which Applicants do not admit), Packer, Leiper, Rose, Hemler and Krishnan are still deficient with respect to the above-described features of claim 1. Thus, even in combination, Packer, Leiper, Rose, Hemler and Krishnan fail to render claim 11 obvious.

Therefore, Applicants respectfully request that the rejection of claim 11 under 35 U.S.C. § 103 be withdrawn.

6. Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler, and Massaro et al. (US 2002/0087329), hereinafter "Massaro."

The Examiner correctly acknowledges that the features of claim 12 are absent from Packer, Leiper, Rose and Hemler, but alleges that these features are taught by Massaro, thereby rendering claim 12 obvious to one of ordinary skill at the time of the invention. Even assuming *arguendo* that the features of claim 12 are taught by Massaro (which Applicants do not admit) and that Massaro could be properly combined with Packer, Leiper, Rose and Hemler (which Applicants do not admit), Packer, Leiper, Rose, Hemler and Massaro are still deficient with respect to the above-described features of claim 1. Thus, even in combination, Packer, Leiper, Rose, Hemler and Massaro fail to render claim 12 obvious.

Therefore, Applicants respectfully request that the rejection of claim 12 U.S.C. § 103 be withdrawn.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Donald J. Daley at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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By


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